

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Issiah J. Fidler et al.

Serial No.: 10/532,551

Filed: March 30, 2006

For: ACTIVE SPECIFIC IMMUNOTHERAPY  
OF CANCER METASTASIS

Group Art Unit: 1647

Examiner: Unknown

Atty. Dkt. No.: UTSC:767US

**CERTIFICATE OF ELECTRONIC SUBMISSION**

**DATE OF SUBMISSION:** October 9, 2008

**INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:


In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. § 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. § 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSC:767US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: October 9, 2006

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| Form PTO-1449 (modified)  |   | Atty. Docket No.<br>UTSC:767US              | Serial No.<br>10/532,551 |
| List of Patents and Publications for Applicant's<br><br>INFORMATION DISCLOSURE STATEMENT<br><br>(Use several sheets if necessary) |   | Applicant<br>Isaiah J. Fidler <i>et al.</i> |                          |
|   |   | Filing Date:<br>March 30, 2006              | Group:<br>1647           |
| U.S. Patent Documents<br><i>See Page 1</i>  | Foreign Patent Documents<br><i>See Page 1</i> | Other Art<br><i>See Page 1</i>              |                          |

## U.S. Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date     | Name                    | Class | Sub Class | Filing Date of App. |
|-------------|-----------|-----------------|----------|-------------------------|-------|-----------|---------------------|
|             | A1        | 4,215,051       | 07/29/80 | Schroeder <i>et al.</i> | 260   | 346.7     | 08/29/79            |
|             | A2        | 4,745,051       | 05/17/88 | Smith <i>et al.</i>     | 435   | 68        | 05/27/83            |
|             | A3        | 4,879,236       | 11/07/89 | Smith <i>et al.</i>     | 435   | 235       | 04/16/87            |
|             | A4        | 5,077,214       | 12/31/91 | Guarino <i>et al.</i>   | 435   | 240.2     | 07/07/89            |
|             | A5        | 5,098,702       | 3/24/92  | Zimmerman <i>et al.</i> | 424   | 85.21     | 6/26/89             |
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|             | A7        | 5,162,222       | 11/10/92 | Guarino <i>et al.</i>   | 435   | 240.2     | 09/17/90            |
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## Foreign Patent Documents

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|-------------|-----------|-----------------|----------|---------|-----------------------------|
|             | B1        | JP 6166635      | 06/14/94 | Japan   | Japanese (English Abstract) |
|             | B2        | WO 00/20561     | 04/13/00 | WIPO    | English                     |
|             | B3        | WO 00/55345     | 09/21/01 | WIPO    | English                     |
|             | B4        | WO 01/92484     | 12/06/01 | WIPO    | English                     |
|             | B5        | WO 89/01038     | 02/09/89 | WIPO    | English                     |
|             | B6        | WO 93/07906     | 04/29/93 | WIPO    | English                     |
|             | B7        | WO 98/25574     | 06/18/98 | WIPO    | English                     |

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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|             | B8        | WO 99/24049     | 05/20/99 | WIPO    | English  |

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|-------------|-----------|--|
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|             | C2        | Bernards, <i>et al.</i> , "Effective Tumor Immunotherapy Directed Against An Oncogene-Encoded Product Using A Vaccinia Virgus Vector," <i>Proc. Nat'l Acad. Sci. USA</i> , 84:6854-6858, 1987.   |
|             | C3        | Blissard and Rohrmann, "Baculovirus Diversity and Molecular Biology," <i>Annu. Rev. Entomol.</i> 35:127-155, 1990.   |
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|             | C8        | Columbo <i>et al.</i> , "Immunotherapy I: Cytokine gene transfer strategies," <i>Cancer and Metastasis Reviews</i> , 16:421-432, 1997.   |
|             | C9        | DeGiovanni <i>et al.</i> , "Immunological and Non-Immunological Influence of H-2K <sup>b</sup> Gene Transfection On The Metastatic Ability of B16 Melanoma Cells," <i>Int. J. Cancer</i> , 48:270-276, 1991.                                       |

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|             | C11       | Dong <i>et al.</i> , "Suppression of Angiogenesis, Tumorigenicity, and Metastasis by Human Prostate Cancer Cells Engineered to Produce Interferon- $\beta$ ," <i>Cancer Res.</i> , 59: 872-879, 1999.  |
|             | C12       | Dong <i>et al.</i> , "Suppression Of Tumorigenicity And Metastasis In Murine UV-2237 Fibrosarcoma Cells By Infection With A Retroviral Vector Harboring The Interferon-Beta Gene," <i>Cancer Immuno. Immunother.</i> , 46: 137-146, 1998.                                  |
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|             | C19       | Fidler, "Critical determinants of cancer metastasis: rationale for therapy," <i>Cancer Chemother. Pharmacol.</i> , 43 suppl:S3-S10, 1999.  |
|             | C20       | Flannery and Sandy, "Aggrecan catabolism in cartilage: Studies on the nature of a novel proteinase (aggrecanase) which cleaves the Glu373-Ala374 bond of the interglobular domain," 39 <sup>th</sup> Annual Meeting of Orthopaedic Research Society, page 190, 1993.       |
|             | C21       | Gariglio <i>et al.</i> , "Therapeutic uterine-cervix cancer vaccines in humans," <i>Arch. Med. Res.</i> , 29:279-284, 1998.  |

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|             | C30       | Hu <i>et al.</i> , "Characterization of a Recombinant Vaccinia Virus Expressing Human Melanoma-Associated Antigen p97," <i>J. Virol.</i> , 62: 176-180, 1988.  |
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|             | C32       | Kidd and Emery, "The use of baculoviruses as expression vectors," <i>Appl. Biochem. Biotechnol.</i> , 42:137-159, 1993.  |
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|             | C34       | Kozuma and Hakuwara, "Fusion Characteristics of a Nuclear Polyhedrosis Virus in Cultured Cells: Time Course and Effect of a Synergistic Factor and pH," <i>J. Invert. Pathol.</i> , 63:63-67, 1994.   |
|             | C35       | Kuzio <i>et al.</i> , "Nucleotide Sequence of the p10 Polypeptide Gene of <i>Autographa californica</i> Nuclear Polyhedrosis Virus," <i>Virology</i> , 139:414-418, 1984.   |
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|             | C38       | Lu <i>et al.</i> , "Insect cells transduced with a baculoviral vector encoding murine interferon- $\beta$ as a novel therapeutic cancer vaccine," ABSTRACT, <i>UT MD Anderson Cancer Center, Houston, TX</i> .  |
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|             | C40       | Martignoni <i>et al.</i> , " <i>Baculovirus of Autographa californica</i> (Lepidoptera: Noctuidae): a Candidate Biological Control Agent for Douglas-Fir Tussock Moth (Lepidoptera: Lymantriidae)," <i>J. Econ. Entomol.</i> , 75:1120-1124, 1982.            |
|             | C41       | McCluskie <i>et al.</i> , "Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates," <i>Mol. Med.</i> , 5:287-300, 1999.  |
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|             | C43       | Naftzger <i>et al.</i> , "Immune response to a different antigen induced by altered antigen: a study of tumor rejection and autoimmunity," <i>Proc. Natl. Acad. Sci., USA</i> , 93:14809-14814, 1996.   |
|             | C44       | Ozawa <i>et al.</i> , "Regression of primary murine colon cancer and occult liver metastasis by intralesional injection of lyophilized preparation of insect cells producing murine interferon-beta," <i>Int. J. Oncol.</i> , 22:977-984, 2003.               |
|             | C45       | Ozawa <i>et al.</i> , "Suppression of orthotopic murine colon cancer and liver metastasis by a baculoviral vector system-mediated interferon-beta gene therapy," <i>American Association for Cancer Research</i> , 42:818 (abstract #4390), 2001.             |

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|             | C46       | Pardoll, "Cancer Vaccines," <i>Immunol. Today</i> , 14:310-316, 1993.  |
|             | C47       | Pardoll, <i>et al.</i> , "New Strategies for Active Immunotherapy with Genetically Engineered Tumor Cells," <i>Curr. Opin. Immunol.</i> , 4:619-623, 1992.   |
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|             | C56       | Singh <i>et al.</i> , "Cell Density-Dependent Modulation of Basic Fibroblast Growth Factor Expression by Human Interferon- $\beta$ ," <i>Int. J. Oncol.</i> , 8:649-656, 1996.   |
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| List of Patents and Publications for Applicant's<br><br>INFORMATION DISCLOSURE STATEMENT<br><br>(Use several sheets if necessary) |   | Applicant<br>Isaiah J. Fidler <i>et al.</i> |                          |
|   |   | Filing Date:<br>March 30, 2006              | Group:<br>1647           |
| U.S. Patent Documents<br><i>See Page 1</i>  | Foreign Patent Documents<br><i>See Page 1</i> | Other Art<br><i>See Page 1</i>              |                          |

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam.<br>Init. | Ref.<br>Des. | Citation  |
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|                | C71          | Xie <i>et al.</i> , "Abrogation of Tumorigenicity and Metastasis of Murine and Human Tumor Cells by Transfection with the Murine <i>IFN-β</i> Gene: Possible Role of Nitric Oxide," <i>Clin. Cancer Res.</i> 3:2283-2294, 1997. |

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